EXPERIMENTAL REPORT

DROPLET SIZE DISTRIBUTION FOR P1 THS 2.2 AND MENTHOL TEST ITEMS USING A VALIDATED PIXE CASCADE IMPACTOR

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TABLE OF CONTENTS

1 APPROVAL AND VERIFICATION 3
2 ABSTRACT 3
3 INTRODUCTION 3
4 RESEARCH QUESTION 4
5 PLAN 4
5.1 Approach 4
5.2 Experiment 4
5.3 Design 4
5.4 Samples 4
5.5 Instruments and Materials 5
5.6 Procedure 5
5.7 Data Processing 5
5.8 Respirability acceptance criteria based on aerosol measured MMAD and GSD 5
6 RESULTS 7
7 DISCUSSION AND CONCLUSIONS 9
8 REFERENCES 10
9 REVISION HISTORY 10
10 ABBREVIATIONS 11

TABLE OF TABLES

Table 1: Test item description 5
Table 2: MMAD and GSD upper limit values for which the aerosol is respirable (assuming lognormal distribution) 6
Table 3: MMAD and GSD values for Day 1 - 08.04.2016 (B-25902 / 412379112) 7
Table 4: MMAD and GSD values for Day 2 – 15.04.2016 (B-25901 / 412374718) 8
Table 5: MMAD and GSD values for Day 3 – 18.04.2016 (B-25900 / 412381531) 8

TABLE OF FIGURES

Figure 1: MMAD plotted as a function of GSD (unitless) values. The different data point symbols are linked to the three batch numbers displayed in the insert of the Figure. 9

1 APPROVAL AND VERIFICATION

Name	Justification	Date / Signature
Pratte, Pascal	approved by author, Manager Aerosol Physics	06 June 2016 Pascal Pratte
Goujon, Catherine	approved by owner, Manager Analytical Development and Applications	06 JUNE 2016
Moores, Shelley	verified by Quality Assurance, Manager QA Assessment & Quality Systems	06-June-2016 S. Moores

2 ABSTRACT

The current report documents Droplet Size Distribution (DSD) data for P1 THS2.2 and menthol test items. From the experiments, it was shown that aerosols generated from three tested batches were respirable, meaning smaller than 2.5 µm in Mass Median Aerodynamic Diameter (MMAD).

3 INTRODUCTION

The Droplet Size Distribution (DSD) influences the deposition pattern in the respiratory tract of inhaled aerosols. This assay is used to determine the DSD of the aerosol generated from P1 THS 2.2 device using menthol test items (see Table 1). This assay is based on the use of a cascade impactor to gravimetrically determine the DSD. This instrument was chosen due to its large DSD size range (60nm – 16µm).

4 RESEARCH QUESTION

Is the DSD in the respirable range for P1 device using menthol test items (THS 2.2 Dorado I Vinny Low)?

5 PLAN

5.1 Approach

The experimental approach is described in details in the work instruction named“ Droplet Size Determination using the PIXE Cascade Impactor”.

5.2 Experiment

Experiments were performed from April 8th 2016 to April 18th 2016.

5.3 Design

Described in the experimental protocol (DSD Protocol Menthol).

5.4 Samples

Prior conducting the aerosol generation experiment, samples were conditioned according to ISO conditions for both 3R4F and P1 menthol test items. Ten replicates were performed for three distinct batches over three different days. The laboratory condition set during the aerosol generation was maintained at 22°C ± 2°C and 60% ± 5% relative humidity. The aerosol was generated under Health Canada smoking regimen (Health Canada, T-115, 1999).

Table 1: Test item description

Product/ test item	Consumable Batch number	Manufacturing date	Additional information
THS 2.2 Dorado I Vinny Low	B-25900 / 41.2381531	21 Dec 2015	- RLS-ZRH-2016-94 - TO-10829 - batch device: B-23172 - device: DV.000174(7) - 10 replicates per batch
	B-25901 / 41.2374718	22 Dec 2015	
	B-25902 / 41.2379112	16 Dec 2015	

5.5 Instruments and Materials

Measurements and analyses performed using working instruction named“ Droplet Size Determination using the PIXE Cascade Impactor”.

5.6 Procedure

Described in the experimental protocol (DSD Protocol Menthol).

5.7 Data Processing

Described in the experimental protocol (DSD Protocol Menthol).

5.8 Respirability acceptance criteria based on aerosol measured MMAD and GSD

The key objective of performing these tests was to ensure that aerosols are respirable which means that more than 80% of the total inhaled aerosol is transferred in the human lung alveolar region. Table 2 summarizes the different (MMAD, GSD) couples for which the aerosol is respirable. Each member of each couple represents the maximum value for which the aerosol is respirable. For example, for a GSD of 1.6, the MMAD should not exceed 0.9 µm in order to classify the aerosol as respirable, considering the method variability (see Table 2, right column). For a perfectly mono-disperse aerosol (GSD = 1.0), the maximum possible MMAD characterizing it respirable is 2.5 µm.

Table 2: MMAD and GSD upper limit values for which the aerosol is respirable (assuming lognormal distribution)

Theoretical upper limit values		Upper limit values for MMAD taking into account method variability
MMAD [µm]	GSD [-]	MMAD [µm]
2.5	1.0	2.4
2.1	1.1	2.0
1.7	1.2	1.6
1.5	1.3	1.4
1.3	1.4	1.2
1.1	1.5	1.0
1.0	1.6	0.9
0.9	1.7	0.8
0.8	1.8	0.7
0.7	1.9	0.6
0.6	2.1	0.5
0.5	2.3	0.4
0.4	2.6	0.3
0.3	3.0	0.2

6 RESULTS

From the obtained DSD, the MMAD and the GSD values were calculated and reported in the current section. Briefly, the MMAD is a representative size parameter of the DSD whereas the GSD quantifies how the mass spreads around the MMAD. By definition, a GSD between 1.0 and 1.2 characterizes a mono-disperse distribution otherwise above this range, it is a poly-disperse distribution. The calculated MMAD and GSD values obtained for the three testing days are summarized in Table 3, Table 4 and Table 5. From the Tables, MMADs were found to range from 0.54 to 0.75 µm while the related Geometric Standard Deviation (GSD) parameter was comprised between 1.25 and 1.41.

Table 3: MMAD and GSD values for Day 1 - 08.04.2016 (B-25902 / 412379112)

Replicate	MMAD [µm]	GSD [-]
1	0.57	1.40
2	0.62	1.36
3	0.60	1.38
4	0.62	1.39
5	0.62	1.36
6	NA	NA
7	0.54	1.39
8	0.56	1.41
9	0.58	1.37
10	0.60	1.37

- No sufficient mass was accumulated in the PIXE cascade impactor for replicate 6 to obtain a MMAD and a GSD value.

Table 4: MMAD and GSD values for Day 2 – 15.04.2016 (B-25901 / 412374718)

Replicate	MMAD [µm]	GSD [-]
1	0.66	1.32
2	0.60	1.37
3	0.69	1.38
4	0.75	1.34
5	0.73	1.38
6	0.73	1.37
7	0.72	1.37
8	0.64	1.33
9	0.66	1.41
10	0.70	1.37

Table 5: MMAD and GSD values for Day 3 – 18.04.2016 (B-25900 / 412381531)

Replicate	MMAD [µm]	GSD [-]
1	0.64	1.33
2	0.66	1.30
3	0.73	1.36
4	0.63	1.25
5	0.74	1.36
6	0.66	1.31
7	0.66	1.33
8*	0.67	1.35
9	0.73	1.36
10	0.69	1.34

7 DISCUSSION AND CONCLUSIONS

According to the respirability criteria defined in section 5.8, MMAD and GSD couples were plotted from Table 3, Table 4, Table 5 and compared to upper limit couples from Table 2 as shown in Figure 1. From the Figure, it is observed that the data point for the three tested batches (B-25900, B-25901, and B-25902) are below the dashed curve defining the respirability limit for an aerosol. Based on that, we conclude that aerosols generated from the three batches were respirable.

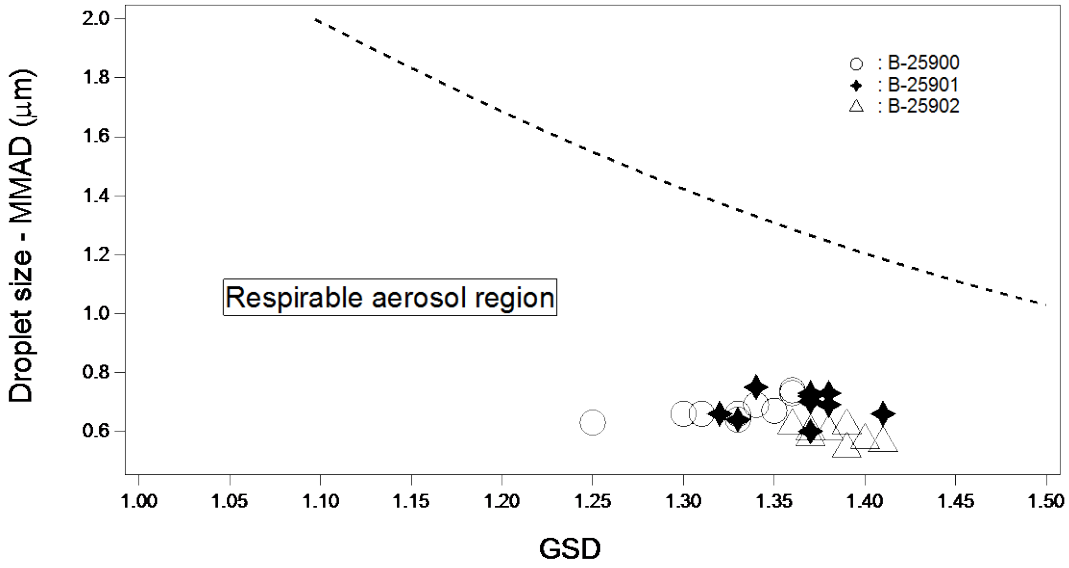


Figure 1: MMAD plotted as a function of GSD (unitless) values. The different data point symbols are linked to the three batch numbers displayed in the insert of the Figure.

8 REFERENCES

- DSD Protocol Menthol
- Health Canada, Official Method T-115, Determination of "Tar", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke, December 31, 1999
- Aerosol Technology,W.C. Hinds, second edition

9 REVISION HISTORY

Version N°	Description of change	Type of change
1.0	Original issue (signed on April 26th 2016)	1
2.0	After version 1.0 was issued, minor typo errors were found. Consequently, a new version 2.0 was issued after the text was corrected.	1
3.0	Some links and references were removed from the text and addtional references were added.	1
4.0	In Table 2, Table 3, Table 4 and Table 5 “units” were added in the column title as “[µm]” for MMAD and “[-]” for GSD, meaning an unitless value.	1

(1. Major change/new version; 2. Minor change; 3. Review without change)

10 ABBREVIATIONS

Abbreviations		
DSD	:	Droplet Size Distribution
GSD	:	Geometric Standard Deviation
MMAD	:	Mass Median Aerodynamic Diameter
MRTP	:	Modified Risk Tobacco Product
P1		Platform 1
PDSP	:	Programmable Dual Syringe Pump
PM2.5	:	Particulate Matter
THS	:	Tobacco Heated System